

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 46D0687259	<b>(X3) Date Survey Completed</b> 09/29/2022
<b>Name of Provider or Supplier</b> Allen-Taintor Dermatology Ogden Clinic	<b>Street Address, City, State</b> 3860 Jackson Ave Ste #2, South Ogden, UT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the lab manager, the laboratory failed to verify the accuracy for microscopic scabies wet mount, Tzanck smear, and potassium hydroxide (KOH) preparations twice a year in 2021. The laboratory performed approximately 154 microbiology tests annually. Finding include: 1. During a record review the laboratory failed to verify the accuracy of wet mounts for scabies, Tzanck smear, and KOH at least twice a year in 2021. 2. Interview with the lab manager on 09/29/2022, at 1:30 PM confirmed the laboratory failed to verify the accuracy of microscopic wet mount scabies, Tzanck smear, and KOH two times per year.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and interview with the lab manager, the laboratory failed to ensure that tissue marking dyes were not used past their expiration date. The laboratory performed approximately 250 histopathology tests annually. Findings: 1. Direct observation of tissue marking dyes on 09/29/2022 at 1:48 PM revealed that 7 of 7 tissue marking dyes had expired. Four dyes had an expiration date of 2022-01-31.</p>

Three dyes had an expiration date of 2021-12-31. 2. Interview with the lab manager on 09/29/2022 at 1:50 PM confirmed the tissue marking dyes were being utilized for patient testing past their expiration date.

**D5449**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on record review and interview with the lab manager, the laboratory failed to perform control procedures each day patient specimens are examined for potassium hydroxide (KOH) preparations. The laboratory performed approximately 150 mycology tests annually. Findings include: 1. A review of laboratory records revealed the laboratory failed to include records of positive and negative control procedures being performed for KOH preparations each day of patient testing since the last survey on 11/07/2019. 2. An interview on 09/29/2022, at 2:18 PM, with the lab manager confirmed the laboratory failed to perform control procedures each day patient specimens were examined for KOH preparations.